Proposed Respiratory Sciences (RES) Integrated Review Group

Summary of Public Comments

The Respiratory Sciences (RES) Study Section Boundaries Team met from October 27 - 29, 2002, to design the study sections of the proposed RES Integrated Review Group (IRG 19) and <u>draft proposed guidelines</u>. These guidelines were made available for public comment on the Center for Scientific Review (CSR) Web site for a 12-week period that ended in February 2003. CSR also received correspondence concerning the organization of this IRG and the feedback from those letters is included in this summary.

<u>APPROVAL</u>

CSR received a number of comments supporting the design of the new Respiratory Sciences IRG, such as, "The working group is to be congratulated for doing such a good and comprehensive job."

COMMENTS ON ALTERNATIVE ORGANIZATIONAL OPTIONS

Most individuals who commented on the alternative suggestions voiced support for moving vascular biology from the Lung Injury Repair and Remodeling (LIRR) study section to the Respiratory Integrative Biology and Translational Research (RIBT) study section, in the event that the LIRR exceeds the maximum number of applications or RIBT falls below the applications necessary to efficiently run a study section. It was also noted that, "Any way you slice it there will be overlap among grants sent the three study sections; no one way will be perfect.... shifting one or two areas that represent the highest level of biological organization from LIRR to RIBT is a reasonable approach..."

Other commenters disapproved of the option noting that, 'It doesn't make sense to "arbitrarily" move certain applications such as those dealing with vascular biology to RIBT.It would be inappropriate for a cellular vascular proposal to be reviewed by a physiologist.", and, "...moving pieces of one to another to balance the numbers is not going to be in the best interest of the science and in this case is somewhat illogical.It doesn't make much sense to separate lung fluid balance from the pulmonary vasculature/lymphatics. Lung fluid balance is much more closely related to the vasculature than to airways." This commenter suggested, "...that if an alternate approach is needed it should be done with the same care and rigor that went into the 3 study sections that the boundaries committee recommended.

OMISSIONS AND SUGGESTIONS

Commenters suggested that the following subject areas were omitted from or need expansion in the RES guidelines. Among those comments were several from individuals interested in expanding the study sections to include more clinical and translational grants:

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- There should be a separate section devoted to clinical trials including Phase I, II and III. With this new format, proposals for pediatric studies and clinical trials will not get optimal review.
- Dedicate one study section to all randomized therapeutic trials, regardless of size, since the critical design issues are the most important issues in review.
 Would not a fourth study section stimulate this mandate?
- The current study sections have no place where clinical research, particularly as relates to genomics and genotype/phenotype, can/will be competently reviewed...the format allegedly has a spot, but there needs to be emphasis on making sure these topics get the necessary attention.
- Translational research, by its nature, is more complicated and less focused...since these proposals are more complicated, there should be fewer grants for this study sections. The individuals should not have their packets containing in vitro studies, which, by their nature, are highly focused and much less complicated.

Commenters also offered the following concerning other subject areas they felt were excluded:

- Immuno-neural interaction should be included in both LCMI and RIBT study sections. Both the immune and the nervous systems are major players in protecting the lungs, and the interaction between these two systems is very important in regulating the various airway functions.
- Because of the special nature and function of the pulmonary defense mechanism bioterrorism should be taken into consideration.
- Where behavioral studies would be reviewed?
- There may be a deficiency concerning applications proposing newer technologies such as 1) digital science - simulation and modeling of lung cell function; and 2) molecular targets for drug discovery.
- There is an under-representation of bioengineering expertise in this area. There
 is a growing need to develop interdisciplinary expertise in bioengineering and cell
 biology.

STUDY SECTION SPECIFIC COMMENTS

General Boundaries

- There could be confusion regarding which study section is most appropriate for
 occupational lung diseases. A proposal pertaining to say occupational asthma
 could be randomly assigned to either LIRR or RIBT. Assign all grant proposals
 for this topic to one section or the other (RIBT seems most reasonable for human
 studies). Alternatively, if there are rules set for assigning the proposals, this
 could work. For example, experimental investigations could be assigned to LIRR
 and human studies to RIBT.
- The distinction between LCMI and LIRR seems fuzzy and arbitrary. Many
 proposals could fall through the cracks (e.g., airway remodeling in CF, impact of
 neonatal inflammation on normal lung development/neonatal lung disease, basic
 cell/molecular biology of fibroblasts with regard to their potential role in
 remodeling).

- Separation of pulmonary endothelial cell biology (PECB) from that of all other lung cells would seem capricious and unwise. PECB should be reviewed by LCMI. If the workload is too high separate the study of inflammatory cells and assign that to LIRR.
- The reviewers' load (in terms of the number of applications assigned to each reviewer per meeting) would be considerably higher in the LCMI than that in the RIBT. To balance the distribution of reviewers' load, some of the specific areas currently included in the LCMI could be merged into the RIBT. Even though certain questions addressed in the applications appear to be investigated primarily at the cellular, sub-cellular or molecular level, the working hypothesis can only be adequately tested in the "integrated" system. To investigate the pathogenic mechanism, the end-points can be properly examined and defined only in the study of whole-animal models and/or humans.
- In the Lung Biology and Pathology (LBPA) study section there was a clear division between Airway/Asthma/inflammation and vascular biology/permeability/other. This is a better division by topics that allows appropriate expertise on each study section with less need for overlap.
- It is more important to keep the cell biology together and the translational applications together. If some of the cell biology goes to translational study sections its review will suffer.

Lung Injury Repair and Regeneration Study Section

- Traditional pulmonary toxicology is not well served. The proposed model does nothing to address toxicology proposals and seeks to dismantle the few toxicology based study sections.
- ARDS, MODS and "sepsis" are related, if not the same, entity. Surgeons
 generate most of these cases through trauma and major operations. The
 appropriate study section needs to include prominent surgical representation.

Respiratory Integrative Biology and Translational Research

- Currently there is no IRG familiar with integrative human research or, for that
 matter, with animal studies that have an integrative focus. The proposed
 reorganization has more logical groupings for research proposals.
- It is critical that studies on the diaphragm be reviewed by experts in the field of skeletal muscle biology. Respiratory muscle topics should continue to be reviewed by the current SMB study section. These grants have far more in common with skeletal muscle biology than they do with lung biology.
- Reworded as, "Respiratory neurobiology and the control of breathing including topics such as ... dyspnea and respiratory sensation...." to highlight dyspnea research.
- The scientific review of human research (other than epidemiology and genetics)
 is perceived to suffer in prior study sections constituted largely by basic
 scientists. Unless the RIBT group is to perform the majority of these types of
 reviews, the problem will persist.
- If "translational" is to have any real meaning, then there must be MD clinician/scientists on the study section.
- Attention to the RIBT review membership is needed to protect for adequate nonmolecular expertise.

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 Any recommendation to assign grants related to the epidemiology of respiratory diseases to non-epidemiologic study sections within the proposed Respiratory Sciences (RES) IRG is opposed.